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Comments on Priorities for the Transatlantic Innovation Dialogue

Introduction

The International Center for Technology Assessment (ICTA) is a non-profit, bi-partisan organization committed to providing the public with full assessments and analyses of technological impacts on society. As part of this work, ICTA has encouraged federal regulatory agencies to adopt an accurate, scientific and standardized definition of nanotechnology that encompasses all the sizes of materials that demonstrate changes at the nanoscale, not just those smaller than 100nm, and to regulate emerging nanotechnologies as they would other materials whose safety has not been determined.

ICTA has been actively working on issues related to nanotechnology for many years. On behalf of coalitions of public interest organizations, ICTA has filed separate legal petitions with both FDA and EPA calling for the regulation of nano-enabled products. Additionally, ICTA co-chairs the Nanotechnology Task Force of the Transatlantic Consumer Dialogue, a forum of US and EU consumer organizations, which collaboratively develops policy recommendations to the US government and the European Union to promote the consumer interest in EU and US policy making. In June 2009, the Transatlantic Consumers Dialogue adopted its *Resolution on Consumer Products Containing Nanoparticles*, urging the EU and US to convene intensive consultations among the relevant regulatory bodies on both sides of the Atlantic to exchange data and establish sound approaches to assessing and preventing risks from nanotechnology.[i]

Nanotechnology: A Transatlantic Dialogue

Governments, universities, and businesses around the world are racing to commercialize nanotechnologies and nanomaterials. Already, over 1,000 consumer products either contain nanomaterials (nano-scale chemicals) in the finished product or are made using

nanotechnologies. At the same time, mounting evidence indicates that this new materials revolution poses significant health, safety, and environmental hazards as well as profound social, economic, and ethical challenges. While the commercialization of nanoproducts and nanotechnologies progresses rapidly, the research needed both to clarify and reduce risks and to develop urgently needed ethical, legal and regulatory oversight mechanisms has barely begun. These mechanisms are required if we are to avoid repeating failures of past "wonder" materials and technologies.

Policies for the Oversight of Nanotechnology

Below is an overview of the *Principles for the Oversight of Nanotechnologies and Nanomaterials*,[ii] an international declaration agreed upon by a broad coalition of over 80 civil society, public interest, environmental and labor organizations concerned with various aspects of nanotechnology's human health, environmental, social, ethical, and other impacts.

I. A Precautionary Foundation

Governments and businesses in the U.S. and EU have invested enormous resources to nanotechnology research and development (R&D), yet both regulation and transatlantic dialogue are woefully lagging behind commercial release. The small size of engineered nanomaterials can imbue them with novel physical, chemical, and biological properties that that are potentially useful; however, the comparatively high reactivity, mobility, and other properties that come with small size are also likely to impart novel toxicity.[iii] Existing research on the impacts of nanomaterials on human health and the environment has raised red flags that warrant precautionary action and further study.[iv] The EU has begun to incorporate the Precautionary Principle into its chemical regulations, while the U.S. regrettably lags on chemical reform. This disparity will undoubtedly place tremendous trade relations and regulatory strain on both sides of the Atlantic unless mutually agreed upon policies are underpinned by the Precautionary Principle.[v]

II. Mandatory Nano-specific Regulations

A modified, or *sui generis*, nano-specific regulatory regime must be an integral aspect of the development of nanotechnologies. Considering the already advanced and rapidly expanding development and commercialization of nanomaterials, a transatlantic assessment of current oversight mechanisms is urgently needed, taking into account the novel properties exhibited by nanomaterials. Furthermore, regulatory actions should retroactively cover all nanomaterial products already on the market.

Voluntary initiatives are wholly inadequate to oversee nanotechnology. Voluntary programs lack incentives for "bad actors" or those with risky products to participate, thus leaving out the entities most in need of regulation.[vi] Under voluntary initiatives, companies may lack motivation to test for long-term or chronic health and environmental effects.[vii] Voluntary initiatives often delay or weaken essential regulation, forestall public involvement, and limit public access to vital environmental safety and health data. For these reasons, the public overwhelmingly prefers mandatory regulatory oversight to voluntary initiatives.[viii] Additionally, the EU and U.S. should establish mandatory reporting schemes to keep track of the introduction into the marketplace of manufactured nanomaterials and exchange information obtained about products being introduced.

III. Health and Safety of the Public and Workers

Adequate and effective nanomaterial oversight requires an immediate emphasis on preventing known and potential exposures to nanomaterials that have not been proven safe. This is essential for both the public and nano-industry workers because some materials present potential hazards and others are largely untested. Free nanoparticles (nanomaterials that are not bound up in other materials) are of particular concern because they appear most likely to enter the body, react with cells, and cause tissue damage.[ix] Embedded nanoparticles also pose exposure concerns. Workers may be exposed to such materials throughout the manufacturing process, and disposal and recycling activities may expose the public and the environment.

IV. Environmental Sustainability

A nanomaterial lifecycle assessment[x] – including manufacturing, transport, product use, recycling, and disposal into the waste stream – is necessary to understand how various statutory systems apply and where regulatory gaps exist.[xi] Full lifecycle environmental, health and safety effects must be assessed prior to commercialization.

Once loose in nature, manufactured nanomaterials represent an unprecedented class of manufactured pollutants. Potentially damaging environmental impacts can be expected to stem from the novel nature of manufactured nanomaterials, including mobility and persistence in soil, water and air, bioaccumulation, and unanticipated interactions with chemical and biological materials.[xii] The limited number of existing studies has raised red flags, such as exposure to high levels of nanoscale aluminum stunting root growth in five commercial crop species,[xiii] byproducts associated with the manufacture of single-walled carbon nanotubes causing increased mortality and delayed development of a small estuarine crustacean,[xiv] and damage to beneficial microorganisms from nanosilver.[xv] The U.K. Royal Society has recommended that, "the release of nanoparticles and nanotubes in the environment be avoided as far as possible," and that, "factories and research laboratories treat manufactured nanoparticles and nanotubes as hazardous, and seek to reduce or remove them from waste streams."[xvi]

V. Transparency

Assessment and oversight of nanomaterials requires mechanisms ensuring transparency, including labeling of consumer products that contain nanomaterials, installing workplace right to know laws and protective measures, and developing a publicly accessible inventory of health and safety information. Polls show that the vast majority of the public lacks even basic information about nanotechnology or the presence of nanomaterials in consumer products.[xvii]

The public's right to know requires the labeling of all products containing nanomaterial ingredients.[xviii] Moreover, product labeling facilitates documentation of potential environmental releases, human exposures, and accountability for adverse impacts. On November 20, 2009, The Council of the European Union, the EU's main decision-making body, issued a new regulation requiring cosmetics manufacturers to label any nanoparticles contained in products marketed within the European Union.[xix] Transatlantic dialogue on nanotechnology and transparency is urgently needed; the EU has taken positive

steps in regards to transparency and now the U.S. must catch up in order to remain competitive in the global marketplace.

Safety testing data must be available for public scrutiny. In light of the industry's poor record in preventing workplace exposures and environmental releases of hazardous chemicals, effective oversight should include strictures on the use of confidentiality shields for nanomaterials. The provisions of international conventions on public access to information should be respected.[xx]

VI. Public Participation

The potential of nanotechnologies to transform the global social, economic, and political landscape makes it essential that the public fully participate in the deliberative and decision-making processes.[xxi] These processes must be *open*, facilitating equal input from all interested and affected parties. Participation must also be *meaningful*: it must proceed and inform policy development and decision-making, rather than be limited to after-the-fact, one-way public 'engagement' in which the government and/or industry 'educates' the public with the goal of quelling debate and smoothing public acceptance.

Finally, *full* public participation requires democratic involvement for the entire range of processes by which nanotechnologies are developed and used and is necessary at each stage of development on a continuing basis to ensure that public concerns, values and preferences inform and guide nanotechnology oversight. Additionally, special efforts must be made to include persons living in poor communities, who have suffered disproportionately from the development of new technologies in the past.

VII. Inclusion of Broader Impacts

Consideration of nanotechnology's wide-ranging effects, including ethical and social impacts, must occur at each stage of the development process. Adequate assessment of both imports and exports containing nanomaterials is essential.

In addition to posing health, safety and environmental risks, nanomaterials present broader socio-economic concerns. For example, as new nanomaterials gain widespread use, they may disrupt markets for existing commodities, with potentially devastating consequences for the economies of commodity-dependent developing countries (i.e., the poorest countries).[xxii] The adverse impacts of granting patents for fundamental nanomaterials, which may amount to privatizing the building blocks of the natural world, must be considered and addressed. Moreover, the anticipated next generations of nanotechnologies, including the production of more sophisticated nanodevices for manufacturing, military or medical use – including enhancement of human performance – can be expected to pose complex risks as well as social and ethical challenges. Some laboratories are already engineering viruses, yeasts, and bacteria to make nanomaterials. Full public debate on both sides of the Atlantic on all these issues will be crucial.

VIII. Manufacturer Liability

All who market nano-products, including nanomaterial developers, handlers and commercial users, the makers of products containing nanomaterials and retailers who sell nano-containing products to the public, must be held accountable for liabilities incurred from their products. Incorporating and addressing manufacturer liability should be a key area of focus

for any transatlantic dialogue on nanotechnology as many of the nanomaterials are on the market with inadequate testing and their sellers make unsubstantiated claims about their safety and effectiveness.

Forms for Transatlantic Cooperation

1. Transatlantic Data/Knowledge Exchange

In November 2009, the U.S. Environmental Protection Agency (EPA) convened a Scientific Advisory Panel (SAP) to assess and evaluate the hazard and exposure associated with nanosilver and other nanometal pesticide products. The SAP concluded that data gaps about potential exposure and hazards related to nanoparticles are broad; most existing models are not appropriate for use with nanomaterials and will not accurately predict nanomaterial exposure scenarios; and, existing data on current exposure and toxicity studies vary greatly with respect to metrics and particle size, among others. In light of the issues raised by the EPA SAP, transatlantic cooperation on nanotechnology can be approached in many ways and should include:

- Data/knowledge exchange aimed at increasing scientific understanding and facilitating regulatory decision-making. Where gaps or shortfalls in research are recognized, the U.S. and EU should direct and fund research to overcome such gaps.
- Establish common data reporting and product testing methodologies with respect to particle characterization, composition, size, aggregation information and solubility of particles.
- Generate common research goals with an emphasis on environmental, health and safety (EHS) data, focusing on both acute and long-term low-level exposure testing.

2. Regulatory Cooperation for Oversight

As nanomaterials become increasingly pervasive on the global marketplace, it is imperative that representatives of the various U.S. and EU regulatory bodies convene and establish common regulatory goals for the oversight of nanotechnology. Regulatory goals should be based on the *Principles for the Oversight of Nanotechnologies and Nanomaterials* and *The Resolution on Consumer Products Containing Nanoparticles*, and should be crafted in consultation with civil society, public interest, environmental and labor organizations currently focusing on nanotechnology's human health, environmental, social, ethical, and other impacts.

Short-term and Long-term Goals for the Oversight of Nanotechnology

- The U.S. and EU should formalize and agree upon definitions related to nanotechnology. It is crucial to ensure that there is agreement on definitions of what constitute nanoparticles and other relevant nanotechnology-related terms so that a lack of agreed definitions does not further delay the establishment of effective regulation.
- The U.S. and EU should establish mandatory reporting schemes to track the introduction of manufactured nanomaterials and establish an extensive inventory of all current and future nanomaterials used in products on the market. Any inventory must be made publicly available.
- The U.S. and EU should establish research goals and begin addressing data/research gaps as outlined above.
- The U.S. and EU should establish common regulatory goals for the oversight of nanotechnology as outlined above.

Respectfully submitted,

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[i] We urge you to review the Transatlantic Consumers Dialogue resolution on nanotechnology available at: http://tacd.org/index.php?option=com_docman&task=cat_view&gid=75&Itemid=40

[ii] For a complete list of the coalition member organizations as well as the Principles document in full, please visit: http://nanoaction.org/nanoaction/page.cfm?id=223

[iii] See, e.g., Andre Nel et al., Toxic Potential of Materials at the Nanolevel, 311 SCIENCE 622-27, 622, 623 Fig. 1 (2006).

[iv] See, e.g., THE ROYAL SOCIETY AND THE ROYAL ACADEMY OF ENGINEERING, NANOSCIENCE AND NANOTECHNOLOGIES: OPPORTUNITIES AND UNCERTAINTIES (2004); Andre Nel et al., Toxic Potential of Materials at the Nanolevel, 311 SCIENCE 622, 622-23 (2006); Holsapple et al., Research Strategies for Safety Evaluation of Nanomaterials, Part II: Toxicological and Safety Evaluation of Nanomaterials, Current Challenges and Data Needs, 88 TOXICOLOGICAL SCIENCES 12 (2005); Oberdörster et al., Nanotoxicology: an Emerging Discipline from Studies of Ultrafine Particles, 113 ENVIRONMENTAL HEALTH PERSPECTIVES 823 (2005); TRAN et al., INSTITUTE OF OCCUPATIONAL MEDICINE, A SCOPING STUDY TO IDENTIFY HAZARD DATA NEEDS FOR ADDRESSING THE RISKS PRESENTED BY NANOPARTICLES AND NANOTUBES (2005); EUROPEAN COMMISSION'S SCIENTIFIC COMMITTEE ON EMERGING AND NEWLY IDENTIFIED HEALTH RISKS (SCENIHR), *OPINION ON THE APPROPRIATENESS OF EXISTING METHODOLOGIES TO ASSESS THE POTENTIAL RISKS ASSOCIATED WITH ENGINEERED AND ADVENTITIOUS PRODUCTS OF NANOTECHNOLOGIES* 6 (2005); Andrew Maynard, Nanotechnology: The Next Big Thing, or Much Ado about Nothing?, 51 ANNALS OF OCCUPATIONAL HYGIENE 1, 4-7 (2006); J. SASS, NATURAL RESOURCES DEFENSE COUNCIL, NANOTECHNOLOGY'S INVISIBLE THREAT, (2007); FRIENDS OF THE EARTH, NANOMATERIALS, SUNSCREENS AND COSMETICS: SMALL INGREDIENTS, BIG RISKS (2006).

[v] The European Union plans to apply the precautionary principle to issues that may have "potentially dangerous effects on the environment, human, animal or plant health." EUROPEAN COMMISSION, COMMUNICATION FROM THE COMMISSION ON THE PRECAUTIONARY PRINCIPLE (2000).

[vi] See, e.g., British Department for Environment, Food, and Rural Affairs, www.defra.gov.uk/environmental/nanotech (voluntary program launched in September 2006, and as of April 2007, has received only six submissions).

[vii] J. CLARENCE DAVIES, WOODROW WILSON INTERNATIONAL CENTER FOR SCHOLARS, PROJECT ON EMERGING NANOTECHNOLOGIES, EPA AND NANOTECHNOLOGY: OVERSIGHT FOR THE 21ST CENTURY 18 (2007) ("It is hard to see what will motivate manufacturers to carry out chronic and environmental testing if regulation does not require it.").

[viii] JANE MACOUBRIE, WOODROW WILSON INTERNATIONAL CENTER FOR SCHOLARS, PROJECT ON EMERGING NANOTECHNOLOGIES, INFORMED PUBLIC PERCEPTIONS OF NANOTECHNOLOGY AND TRUST IN GOVERNMENT 14 (2005).

[ix] See, e.g., THE ROYAL SOCIETY AND THE ROYAL ACADEMY OF ENGINEERING, NANOSCIENCE AND NANOTECHNOLOGIES: OPPORTUNITIES AND UNCERTAINTIES 36, 79-80 (2004); Oberdörster et al., Principles for Characterizing the Potential Human Health Effects From Exposure to Nanomaterials: Elements of a Screening Strategy, 2 PARTICLE AND FIBRE TOXICOLOGY 8, 29 (2005).

[x] A lifecycle assessment is the "systematic analysis of the resources usages (e.g., energy, water, raw materials) and the emissions over the complete supply chain from the cradle of primary resources to the grave of recycling or disposal." THE ROYAL SOCIETY AND THE ROYAL ACADEMY OF ENGINEERING, NANOSCIENCE AND NANOTECHNOLOGIES: OPPORTUNITIES AND UNCERTAINTIES 32 (2004).

[xi] See, e.g., THE ROYAL SOCIETY AND THE ROYAL ACADEMY OF ENGINEERING, NANOSCIENCE AND NANOTECHNOLOGIES: OPPORTUNITIES AND UNCERTAINTIES 46 (2004) ("Any widespread use of nanoparticles in products such as medicines (if the particles are excreted from the body rather than biodegraded) and cosmetics (that are washed off) will present a diffuse source of nanoparticles to the environment, for example through the sewage system. Whether this presents a risk to the environment will depend on the toxicity of nanoparticles to organisms, *about which almost nothing is known*, and the quantities that are discharged.") (emphasis added); see, also Wardak et al., The Product Life Cycle and Challenges to Nanotechnology Regulation, 3 NANOTECHNOLOGY LAW & BUSINESS 507 (2006). Scientific experts estimated that it might take until 2012 to have "the ability to evaluate the impact of engineered nanomaterials from cradle to grave." Maynard et al., *Safe Handling of Nanotechnology*, Vol 444 NATURE 267-69 (November 16, 2006).

[xii] See, e.g., U.S. ENVIRONMENTAL PROTECTION AGENCY, NANOTECHNOLOGY WHITE PAPER 11 (2006).

[xiii] Yang L. et al., Particle surface characteristics may play an important role in phytotoxicity of alumina nanoparticles, 158(2) TOXICOL LETT. 122-32 (2005).

[xiv] Templeton R. et al., Life-cycle Effects of Single-Walled Carbon Nanotubes (SWNTs) on an Estuarine Meiobenthic Copepod, 40 ENVIRONMENTAL SCIENCE AND TECHNOLOGY 7387-7393. (2006).

[xv] R. SENJEN, FRIENDS OF THE EARTH AUSTRALIA, NANOSILVER – A THREAT TO SOIL, WATER AND HUMAN HEALTH?, (2007) available at http://nano.foe.org.au/; J. SASS, NATURAL RESOURCES DEFENSE COUNCIL, NANOTECHNOLOGY'S INVISIBLE THREAT (2007).

[xvi] See, e.g., THE ROYAL SOCIETY AND THE ROYAL ACADEMY OF ENGINEERING, NANOSCIENCE AND NANOTECHNOLOGIES: OPPORTUNITIES AND UNCERTAINTIES 46 (2004).

[xvii] DAN KAHAN ET AL., WOODROW WILSON INTERNATIONAL CENTER FOR SCHOLARS, PROJECT ON EMERGING NANOTECHNOLOGIES, NANOTECHNOLOGY RISK PERCEPTIONS 2 (2006) ("Consistent with past surveys (Peter D. Hart Research Associates, 2006), the results suggested that Americans are largely uninformed about nanotechnology: 81% of subjects reported having heard either "nothing at all" (53%) or "just a little" (28%) about nanotechnology prior to being surveyed, and only 5% reported having heard "a lot.").

[xviii] See, e.g., Paraco Inc v. Dept of Agriculture, 118 Cal. App. 2d 348, 353-54 (1953) (holding that the public "have a right to know what they are buying"); Fredrick H. Degnan, The Food Label and the Right-to-Know, 52 Food & Drug L.J. 49, 50 (1997) (Pursuant to the 'consumer's right to know', "the public has a basic right to know any fact it deems important about food or a commodity before being forced to make a purchasing decision.").

[xix] European Council: Regulation on cosmetic products (10 November 2009). Available online at: http://register.consilium.europa.eu/pdf/en/09/st03/st03623.en09.pdf

[xx] United Nations Economic Commission for Europe (UNECE), AARHUS CONVENTION, CONVENTION ON ACCESS TO INFORMATION, PUBLIC PARTICIPATION IN DECISION-MAKING AND ACCESS TO JUSTICE IN ENVIRONMENTAL MATTERS, adopted June 25, 1998.

[xxi] See, e.g., NATIONAL SCIENCE AND TECHNOLOGY COUNCIL, NATIONAL NANOTECHNOLOGY INITIATIVE, NANOTECHNOLOGY: SHAPING THE WORLD ATOM BY ATOM 4 (1999) (proclaiming nanotechnology as "a likely launch pad to a new technological era because it focuses on perhaps the final engineering scales people have yet to master."); id. at 8 ("If present trends in nanoscience and nanotechnology continue, most aspects of everyday life are subject to change."); id. ("The total societal impact of nanotechnology is expected to be much greater than that of the silicon integrated circuit because it is applicable in many more fields than just electronics."); id. at 1 (stating the nanotechnology revolution will result in "unprecedented control over the material world."); see also ASIA-PACIFIC ECONOMIC COOPERATION INDUSTRIAL SCIENCE AND TECHNOLOGY WORKING GROUP, NANOTECHNOLOGY: THE TECHNOLOGY FOR THE 21ST CENTURY. VOL II: THE FULL REPORT 24 (2002), ("If nanotechnology is going to revolutionize manufacturing, health care, energy supply, communications and probably defense, then it will transform labor and the workplace, the medical system, the transportation and power infrastructures and the military. None of these latter will be changed without significant social disruption.").

[xxii] See, e.g., THE SOUTH CENTRE, THE POTENTIAL IMPACT OF NANOTECHNOLOGIES ON COMMODITY MARKETS: THE IMPLICATIONS FOR COMMODITY DEPENDENT DEVELOPING COUNTRIES (2005).